

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

THE PROCTER & GAMBLE COMPANY,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant.

Civil Action No. 04-940 (JJF)

STIPULATION

WHEREAS, Plaintiff The Procter & Gamble Co. ("P&G") and Defendant Teva Pharmaceuticals USA, Inc. ("Teva") (collectively "the parties") are engaged in ongoing patent litigation involving U.S. Pat. No. 5,583,122 ("the '122 patent") as it relates to risedronate;

WHEREAS, Teva has filed Abbreviated New Drug Application ("ANDA") No. 77-132 seeking approval from the United States Food and Drug Administration ("FDA") to market generic versions of P&G's risedronate sodium products marketed under the trade name Actonel®;

WHEREAS, the parties recognize that any approval of the ANDA cannot be made until after the expiration of the thirty-month period provided for under paragraph 21 U.S.C. § 355(j)(5)(2)(B)(i) which will end on January 6, 2007 for ANDA No. 77-132;

NOW THEREFORE, the parties hereby stipulate to the following:

(1) If Teva, or any parent, subsidiary, or other related entity of Teva, elects to manufacture, sell, or market in the United States, or import into the United States (other than in accordance with 35 U.S.C. section 271(e)(1)), (1) a product that is the subject of ANDA No. 77-

132 and/or (2) risedronate, either alone or in combination with one or more pharmaceutically acceptable carriers, before:

- (a) A court issues a decision holding that the asserted claims of the '122 patent are invalid, unenforceable or not infringed;
- (b) The '122 patent expires; or
- (c) Any entity other than Teva, or any parent, subsidiary, or other related entity of Teva, sells a generic version of an Actonel® product in the United States, including any entity authorized by P&G to do so;

Teva shall provide thirty (30) days advance notice to P&G, so as to allow P&G, if it so chooses, the opportunity to file a motion for a temporary restraining order and/or preliminary injunctive relief against any such action.

(2) This stipulation contains and constitutes the entire understanding and agreement among the parties with respect to the foregoing subject matter.

RICHARDS LAYTON & FINGER, P.A.

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Dated: December 22, 2006

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Dated: December 22, 2006